Inclusion of Children in NIH Research Protocols

This policy applies to all NIH conducted or supported research involving human subjects, including research that is 'Exempt' in accordance with 45 CFR 46, Sections 101(b) and 401(b).

Effective October 1, 1998, children are to be included in all initial (Type 1) human subject research applications conducted or supported by the NIH, unless there are scientific and ethical reasons for their exclusion.

In compliance with this policy, research protocols submitted for funding to NIH must include either a description of plans for the inclusion of children or an acceptable justification for their exclusion.

In the research protocol, the investigator should create a section entitled, "Participation of Children," that describes either:

- The plan to include children and a rationale for selecting or excluding any specific age range of children; or
- The reason(s) for excluding children as participants altogether; or

If children are included, this section must also describe:

- The expertise of the investigative team in handling children of the age indicated; and
- The available facilities to appropriately accommodate children; and
- That a sufficient number of children have been included to contribute to a meaningful analysis (in view of the purpose of the study).

Acceptable justifications for the exclusion of children in research protocols include:

- The research topic to be studied is irrelevant to children.
- There are laws or regulations barring the inclusion of children in the research protocol. For example, the regulations for the protection of human subjects allow consenting adults to accept a higher level of risk than is permitted for children.
- The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. NIH program staff can be contacted for guidance on this issue if the information is not readily available.
- A separate age-specific study in children is warranted and preferable (consult NIH policy for specific examples of such studies).
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgement). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis.
- Study designs aimed at collecting additional data on pre-enrolled adult study participants (e.g. longitudinal follow-up studies that did not include data on children).

Other special cases justified by the investigator and found acceptable to the review group and the Institute Director.
FOOTNOTES:

"Children" are defined by the NIH as individuals under the age of 21. Please note that this is at variance with the New York State law that defines children as individuals under the age of 18. Parental consent is not required for individuals who are at least 18 years of age.

Scientific review groups at the NIH will assess the acceptability of each protocol with regard to the age-appropriate inclusion or exclusion of children. NIH will also evaluate the research design as it applies to such children.

If you have any questions regarding the requirements for satisfying this policy, you may contact the NIH. The complete policy is available on the world wide web at: 